

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Charles P. Kocoras	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	98 C 3952	DATE	7/13/2000
CASE TITLE	SmithKline Beecham et al vs. Apotex Corp et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

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DOCKET ENTRY:

- (1) Filed motion of [use listing in "Motion" box above.]
- (2) Brief in support of motion due _____.
- (3) Answer brief to motion due _____. Reply to answer brief due _____.
- (4) Ruling/Hearing on _____ set for _____ at _____.
- (5) Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (6) Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (7) Trial[set for/re-set for] on _____ at _____.
- (8) [Bench/Jury trial] [Hearing] held/continued to _____ at _____.
- (9) This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
 FRCP4(m) General Rule 21 FRCP41(a)(1) FRCP41(a)(2).
- (10) [Other docket entry] **ENTER MEMORANDUM OPINION:** Plaintiffs' motion (Doc 95-1) to amend their complaint is granted.

- (11) [For further detail see order attached to the original minute order.]

No notices required, advised in open court.		number of notices <i>JUL 17 2000</i>	Document Number <i>98</i>
No notices required.			
Notices mailed by judge's staff.		docketing deputy initials <i>98</i>	
Notified counsel by telephone.			
Docketing to mail notices.			
Mail AO 450 form.			
Copy to judge/magistrate judge.			
 SCT courtroom deputy's initials		Date/time received in central Clerk's Office <i>7/13/00</i>	mailing deputy initials <i>134</i>

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SMITHKLINE BEECHAM)
CORPORATION and BEECHAM)
GROUP, p.l.c.)
)
Plaintiffs,)
)
vs.) 98 C 3952
) DOCKETED
APOTEX CORP., APOTEX, INC., and)
TORPHARM, INC.,) JUL 17 2000
)
Defendants.)

MEMORANDUM OPINION

CHARLES P. KOCORAS, District Judge:

Before the Court is Plaintiffs' Motion to Amend their Complaint. For the reasons set forth below, Plaintiffs' Motion is granted.

BACKGROUND

Plaintiffs SmithKline Beecham Corporation and Beecham Group, p.l.c. (collectively "SmithKline") filed a one-count patent infringement complaint against Defendants Apotex Corp., Apotex, Inc. and TorPharm, Inc. (collectively "Defendants") on June 26, 1998. Through this motion, SmithKline seeks an order permitting it to amend this complaint.

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We have fully set forth a full rendition of the facts underlying this dispute in several previous opinions, see SmithKline Beecham Corp. v. Apotex Corp., 2000 WL 116082 (N.D. Ill. Jan. 24, 2000); SmithKline Beecham Corp. v. Apotex Corp., 1999 WL 311697 (N.D. Ill. May 13, 1999), thus we will set forth only those facts necessary to the issues raised by the parties.

On January 26, 1988, the United States Patent and Trademark Office granted Beecham Patent No. 4,721,723 ("the '723 Patent"), for an invention called "Anti-Depressant Crystalline Paroxetine Hydrochloride Hemihydrate." Beecham eventually assigned the patent to SmithKline, which markets the paroxetine as a pharmaceutical drug, Paxil. The initial complaint claims that Defendants violated 35 U.S.C. §§ 271(b), 271(e) and 281-283 when SmithKline received a letter from TorPharm, informing and notifying SmithKline that through its United States agent, Apotex Corp., TorPharm had previously filed Abbreviated New Drug Application ("ANDA") No. 75-356 with the United States Food and Drug Administration ("FDA") for "Paroxetine HCl Tablets." The letter claimed to constitute a Notification of Certification of non-infringement under Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and advised SmithKline that unlike the '723 Patent which is in hemihydrate form, because TorPharm's product contained paroxetine hydrochloride solely in an anhydrous state, TorPharm

Division believed that its "Paroxetine HCI Tablets" did not infringe upon the '723 Patent. SmithKline disputes this claim, arguing that paroxetine hydrochloride in an anhydrate state will convert into a hemihydrate form. Accordingly, SmithKline claims that ANDA No. 75-356 for "Paroxetine HCI Tablets" infringes on the '723 Patent.

With fact discovery closed, Plaintiffs now wish to amend their complaint to add allegations that Defendants willfully infringed the '723 Patent, as embodied in proposed paragraphs 15 and 16:

15. Defendants Apotex, Inc, Apotex Corp., and TorPharm, Inc. have willfully infringed the '723 patent.
16. Defendant Apotex, Inc. has willfully directed and/or induced infringement of the '723 patent by defendants Apotex Corp. and Torpharm, Inc.

Plaintiffs also seek to amend their prayer for relief so that it reads as follows:

WHEREFORE, Plaintiffs SB and Beecham demand judgment against Defendants and respectfully requests that this Court enter Orders:

- (a) prohibiting any approval by the FDA of TorPharm's paroxetine HCI tablets on any effective date prior to the date of expiration of the '723 patent, or such later date as the Court may determine;
- (b) enjoining Defendants from the commercial manufacture, use, or sale of its Paroxetine HCI tablets until the expiration of the '723 patent, or such later date as the Court may determine;
- (c) awarding SB and Beecham reasonable attorney fees; and
- (d) awarding SB and Beecham such further and additional relief as this Court deems just and proper;

The impetus of the proposed amendment is the April 18, 2000 deposition of Dr. Bernard Charles Sherman, Defendant Apotex, Inc.'s Chairman, who also exerts de facto control over all the Defendants. Sherman's deposition testimony was that he personally directed Defendants' attempts to circumvent SmithKline's patent to produce and market their paroxetine. Thus, Sherman was aware of the '723 patent and that SmithKline would file suit to enforce it.

Despite this knowledge, Sherman testified that he could not recall consulting with legal counsel on whether Defendants were infringing the '723 patent. Rather, he testified that he formulated his own conclusion that Defendants would not infringe the patent if they utilized the prior art material and produced the paroxetine in an anhydrous state. Sherman subsequently refused to answer whether Defendants obtained a written legal opinion on the '723 patent, but following the advice of counsel, asserted an attorney-client privilege. This motion followed.

DISCUSSION

SmithKline moves to amend its complaint to allege that the Defendant willfully infringed the '723 patent by failing to obtain legal advice prior to filing the ANDA. Defendants argue that it would be futile to permit the amendment, that the amendment is in bad faith, and granting leave to amend would prejudice them.

I. Futility

Federal Rule of Civil Procedure 15(a) provides that a party seeking to amend a pleading must obtain leave of court or written consent of the opposing party. See Garner v. Kinnear Mfg. Co., 37 F.3d 263, 269 (7th Cir. 1994) (citing Perrian v. O'Grady, 958 F.2d 192, 194 (7th Cir. 1992)). District courts may grant leave to amend pleadings under Rule 15(a) of the Federal Rules of Civil Procedure, which absent harm to the other party "shall be freely given when justice so requires." See Fed. R. Civ. Proc. 15(a). Leave to amend is "inappropriate where there is undue delay, bad faith, dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment or futility of the amendment."

Perrian, 958 F.2d at 194; see also General Electric Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1085 (7th Cir. 1997) (citing inter alia Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227 (1962)); Orix Credit Alliance, Inc. v. Taylor Mach. Works, Inc., 125 F.3d 468, 480 (7th Cir. 1997) (citing Ferguson v. Roberts, 11 F.3d 696, 706 (7th Cir. 1993)). Once defendant has answered, it is within the discretion of the district court to allow plaintiff to amend its complaint. See Bowers v. Jones, 978 F.2d 1004, 1008 (7th Cir. 1992).

Defendants do not claim that SmithKline unduly delayed seeking to assert its willful infringement claim, but initially claim that the amendment is futile. It is within the discretion of a district court to deny leave to amend when the proposed amendment is futile. See Garcia v. City of Chicago, Illinois, 24 F.3d 966, 970 (7th Cir. 1994). A proposed amendment is futile when: (1) it does not state a valid liability theory; (2) it is insufficient to withstand a motion to dismiss; (3) it simply uses different language to restate the previously plead facts; or (4) it reasserts a previously determined claim. See Bowers, 978 F.2d at 1008; Garcia, 24 F.3d at 970.

Defendants claim that the proposed amendment is insufficient to withstand a motion to dismiss because willful infringement requires an actual infringement and an ANDA is merely a technical infringement. However, this argument belies the underlying basis of SmithKline's proposed amendment and is contrary to a case directly on point.

The proposed amended complaint evidences that SmithKline does not seek to assert that Defendants' willfully infringed of its patent based on filing its ANDA. Rather, the proposed basis of the willfulness claim is Defendants' alleged failure to secure legal advice prior to filing the ANDA, which we believe is sufficient to survive a motion to dismiss.

Under 35 U.S.C. § 285, a patentee may be awarded reasonable attorney fees in "exceptional cases." One such "exceptional case," is when a willful infringement has occurred. See L.A. Gear, Inc. v. Thom McAn Shoe Co., 988 F.2d 1117, 1128, 25 U.S.P.Q.2d 1913 (Fed. Cir. 1993). If an infringement is determined to have been willful, the patentee may be awarded attorneys fees, or an increased damages amount. See Electro Medical Systems v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1056 (Fed. Cir. 1994). Willfulness is a factual determination made in consideration of the totality of the circumstances, which requires a finding supported by clear and convincing evidence that the infringer acted without regard for the patent and without a reasonable basis for believing that it had a right to act in an infringing fashion. See American Medical Systems, Inc. v. Medical Engineering Corp., 6 F.3d 1523, 1530 (Fed. Cir. 1993) (citing Stickle v. Heublein, Inc., 716 F.2d 1550, 1565, 219 USPQ 377, 378 (Fed. Cir. 1983); Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc., 862 F.2d 1564, 1573, 9 U.S.P.Q.2d 1273, 1282 (Fed. Cir. 1988)).

Evidence that the infringer acted without regard for the patent and without a reasonable basis for believing that it had a right to act in an infringing fashion may be demonstrated by the infringer's failure to obtain adequate legal counsel regarding the patent. An affirmative duty is imposed under the law to refrain from infringing upon known patent rights, which normally requires requesting and obtaining capable

legal counsel prior to undertaking activities that could result in infringing said patent rights. See Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1056, 32 U.S.P.Q.2d 1017 (Fed. Cir. 1994). While there are no inflexible maxims for determining the occurrence of willfulness, see id., and the absence of an opinion by counsel is not outcome determinative, it nonetheless is a primary factor in making the willfulness determination. See Kloster Speedsteel AB v. Crucible, Inc., 793 F.2d 1565, 1579-80, 230 U.S.P.Q. 81, 91 (Fed. Cir. 1986).

Defendants point out that they have not manufactured, used, sold, or offered to sell its anhydrous form of paroxetine hydrochloride. Rather, Defendants have merely filed an ANDA, which is not an actual infringement, but only an artificial one. See Eli Lily & Co. v. Medtronic, Inc., 496 U.S. 661, 675, 110 S.Ct. 2683 (1990). Defendants argue this is insufficient to support a willful infringement claim because such a claim requires an actual infringement. Accordingly, Defendants argue that SmithKline's proposed willful infringement count is futile.

SmithKline counters that Defendants have not cited any controlling, favorable case law, and in contrast, they tender a recent case from the Southern District of New York which supports its argument that a patentee may seek attorneys fees by asserting a willful infringement claim in an ANDA case. See Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 21 F. Supp.2d 366, 48 U.S.P.Q.2d 1741

(S.D.N.Y. 1998). In Yamanouchi, the patentee asserted that the defendant willfully infringed its patent for an anti-ulcer compound by filing an ANDA. See Yamanouchi, 21 F. Supp.2d at 369. Following a bench trial, the court rejected the infringer's argument that a willful infringement action was improper when the infringement at issue consisted of the mere filing of an ANDA. See Yamanouchi, 21 F. Supp.2d at 377, n. 18. The court based its conclusion on Glaxo, Inc. v. Novophram, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997), stating that "the Federal Circuit has elaborated that the ANDA filing represents a substantive infringement if the generic drug that would ultimately be produced under the ANDA would infringe the targeted drug." Yamanouchi, 21 F. Supp. 2d at 377, n. 18. Thus, the court rejected the infringer's argument and permitted the patentee to seek a fee award based on its claim that the infringer willfully infringed the patent at issue by failing to obtain competent legal counsel prior to initiating any possibly infringing activity. See id. at 377.

Finding no error in the court's decision in Yamanouchi, and in the absence of Defendants asserting any contrary case law, there exists a legal basis for SmithKline's willful infringement count against Defendants sufficient to avert an adverse ruling on a motion to dismiss. Thus, we reject Defendant's argument, and hold that it would not be futile to permit SmithKline to assert a willful infringement count against Defendants where the alleged infringement consists of filing an ANDA.

II. Bad Faith & Prejudice

Defendants next argue¹ that permitting SmithKline to pursue a willfulness claim would prejudice them by forcing them to either waive attorney client and work product privileges, or not be able to properly defend their case. They further argue, without citing any supporting authority, that to permit SmithKline to plead and proceed with discovery on the willfulness issue would be tantamount to reversible error. This argument, however, goes against the weight of the law in this District, which condones coinciding discovery on issues of both willfulness and liability. See Dentsply Int'l, Inc. v. Kaydex, 93C20099, 1994 WL 376276 at *1 (N.D. Ill. July 11, 1994); Remcor Prods. Co. v. Servend Int'l, Inc., 93C1823, 1994 WL 594723 (N.D. Ill. Oct. 28, 1994); Caterpillar v. Deere Co., 96C5355, 1997 WL 17798 (N.D. Ill. Jan. 14, 1997) (denying motion to stay willfulness discovery). Further, Defendants' bald proposition that the Seventh Circuit would summarily reverse an order permitting SmithKline to assert a willfulness claim is specious and the case law repudiates it. See Quantum Corp. v. Tandon Corp., 940 F.2d 642, 644 (Fed. Cir. 1991) (Failure

¹Defendants also make a cursory argument that permitting SmithKline to pursue a willfulness claim would be premature because the case is not about past conduct, but future rights. This is essentially the same argument they proffered in support of their unsuccessful claim of futility, which we reject without further comment.

to order separate trial in attorney-client/willful infringement situations does not mandate reversal).

Moreover, Defendants' argument is premature. Permitting SmithKline to amend its complaint to assert a willfulness claim does not force Defendants to choose between asserting their attorney-client privilege and defending this count. Defendants remain free to assert this claim at an appropriate time. Any prejudice to Defendants, if there truly is any, may be avoided by moving for bifurcation of the issues for trial under Federal Rule of Civil Procedure 42, or by moving for an in-camera inspection. This is especially true given the wide latitude afforded courts in managing patent litigation. See Dentsply Int'l, Inc. v. Kaydex, 93C20099, 1994 WL 376276 at *1 (N.D. Ill. July 11, 1994). However, bifurcation is not a foregone conclusion for willfulness/attorney-client privilege cases, even at a later stage of the litigation, see Keyes Fibre Co. v. Packaging Corp. of America, 763 F. Supp. 374, 375, 19 U.S.P.Q.2d 1472 (N.D. Ill. 1991), but warrants consideration when the specific communications at issue demonstrate that a party is confronted with the choice argued by Defendants. Despite these clear pronouncements, Defendants have not provided us with the elements of an attorney-client assertion, much less any communications demonstrating the choice argued by Defendants. Even if we were privy to such

communications, however, the argument remains premature and does not provide a basis for preventing SmithKline from being given leave to amend its complaint.

III. Canadian Litigation

Finally, Defendants argue that Canadian courts has already litigated whether the anhydrous paroxetine will convert to hemihydrate form, and entered judgment for Defendants. The court entered judgment on April 20, 1999. Defendants notified SmithKline of the ANDA in May of 1998, well before the decision of the Canadian Court. Had Defendants obtained this judgment prior to making their determination of whether to file the ANDA, it could have impacted the willfulness determination. See Underwater Devices, Inc. v. Morrison-Knudson Co., 717 F.2d 1380, 1389-90 (Fed. Cir. 1983) (determination of whether infringement will occur must happen before undertaking any potentially infringing acts). However, the law does not provide for 20/20 hindsight retroactively wiping the slate clean and removing the basis for a willfulness claim. See Johns Hopkins University v. Cellpro, Inc., 152 F.3d 1342, 1362-63 (Fed. Cir. 1998). Rather, the relevant arena of analysis will be the reasonableness of the inquiry conducted by Defendants prior to the ANDA letter. Accordingly, the Canadian litigation does not preclude the amendment of SmithKline's complaint.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion to amend their complaint is granted.

Charles P. Kocoras

Charles P. Kocoras
United States District Judge

Dated: July 13, 2000